Notice of Allowability	Application No.	Applicant(s)	
	08/766,350	CHATTERJEE ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *30 June 2004*.

2. ☒ The allowed claim(s) is/are *1-5,20,23,26-30,32-37,39,40,42,43,46-49,51,54-56,59-65,67-76,78-110,125 and 126*.

3. ☒ The drawings filed on *31 December 1996* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20041018* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jill A. Jacobson on October 15, 2004.

2. The application has been amended as follows:

The claims have been amended as follows:

Claim 1 (previously presented): An isolated monoclonal anti-idiotype antibody 11D10 produced by hybridoma cell line ATCC No. HB 12020.

Claim 2 (currently amended): ~~The~~ A labeled antibody comprising the antibody of claim 1, ~~further comprising a~~ wherein said label is capable of producing a detectable signal.

Claim 3 (previously presented): A hybridoma cell line designated ATCC No. HB 12020.

Claim 4 (previously presented): A purified antibody having all the identifying characteristics of antibody produced by a hybridoma cell line according to claim 3.

Claim 5 (original): A hybridoma having all the identifying characteristics of a cell of the hybridoma cell line according to claim 3.

Claims 6-19 (canceled)

Claim 20 (currently amended): A polypeptide having immunological activity of anti-idiotype antibody 11D10, wherein the polypeptide comprises an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of anti-idiotype antibody 11D10, and an immunoglobulin variable region containing three heavy chain CDRs of anti-idiotype antibody 11D10, wherein anti-idiotype antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020 ~~wherein the light chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020, and wherein the heavy chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020~~, and wherein the immunological activity of the polypeptide is an ability to stimulate a specific immune response against human milk fat globule (HMFG).

Claims 21-22 (canceled)

Claim 23 (previously presented): The polypeptide of claim 20, wherein the light chain variable region amino acid sequence is contained in SEQ ID NO:2 and the heavy chain variable region amino acid sequence is contained in SEQ ID NO:4.

Claims 24-25 (canceled)

Claim 26 (previously presented): The polypeptide of claim 20, wherein the polypeptide contains a sequence of at least 2 contiguous amino acids which are identical in forward or reverse orientation to 2 contiguous amino acids of a sequence in human mucin from human milk fat globule (HMFG), wherein said HMFG sequence is contained in SEQ ID NO:33.

Claim 27 (original): A fusion polypeptide comprising the polypeptide of claim 20.

Claim 28 (previously presented): The fusion polypeptide of claim 27 further comprising a cytokine.

Claim 29 (previously presented): The fusion polypeptide of claim 28, wherein the cytokine is granulocyte macrophage colony stimulating factor.

Claim 30 (previously presented): The fusion polypeptide of claim 28, wherein the cytokine is interleukin 2.

Claim 31 (canceled)

Claim 32 (currently amended): The fusion polypeptide of claim 27, wherein the immunoglobulin variable region of the polypeptide of claim 20, containing three CDRs from the light chain variable region of anti-idiotype antibody 11D10, and the immunoglobulin variable region of the polypeptide of claim 20, containing three CDRs from the heavy chain variable region of anti-idiotype antibody 11D10, are linked by a linker polypeptide of about 5 to 20 amino acids.

Claim 33 (previously presented): The fusion polypeptide of claim 27, comprising the light chain variable region and the heavy chain variable region of anti-idiotype antibody 11D10, wherein the light chain variable region and the heavy chain variable region are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim 34 (previously presented): The fusion polypeptide of claim 27 further comprising a heterologous immunoglobulin constant region.

Claim 35 (currently amended): A humanized antibody comprising three CDRs from the light chain variable region of antibody 11D10, three CDRs from the heavy chain variable region of antibody 11D10, and a constant region that is a human sequence, wherein antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020, and wherein the humanized antibody is able to stimulate a specific immune response against human milk fat globule (HMFG), ~~wherein the light chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC No. HB 12020, and wherein the heavy chain variable region~~

~~amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC No. HB 12020~~.

Claim 36 (original): A polymeric 11D10 polypeptide comprising a plurality of the polypeptide of claim 20.

Claim 37 (currently amended): A composition comprising the anti-idiotype antibody ~~11D10~~ of claim 1 and a pharmaceutically acceptable excipient.

Claim 38 (canceled)

Claim 39 (currently amended): A composition comprising a pharmaceutically acceptable excipient and a polypeptide having immunological activity of anti-idiotype antibody 11D10, wherein the polypeptide comprises an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of anti-idiotype antibody 11D10, and an immunoglobulin variable region containing three heavy chain CDRs of anti-idiotype antibody 11D10, wherein anti-idiotype antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020 ~~wherein the light chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020, and wherein the heavy chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020~~, and wherein the immunological activity of the polypeptide is an ability to stimulate a specific immune response against human milk fat globule (HMFG).

Claim 40 (currently amended): An immunogenic composition comprising the anti-idiotype antibody ~~11D10~~ of claim 1 and a pharmaceutically acceptable excipient.

Claim 41 (canceled)

Claim 42 (previously presented): An immunogenic composition comprising the polypeptide of claim 20 and a pharmaceutically acceptable excipient.

Claim 43 (previously presented): The immunogenic composition of claim 40, further comprising an adjuvant.

Claims 44-45 (canceled)

Claim 46 (currently amended): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of ~~monoclonal~~ the anti-idiotype antibody ~~11D10~~ of claim 1 to the individual.

Claim 47 (currently amended): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of the ~~vaccine~~ immunogenic composition of claim 43 to the individual.

Claim 48 (original): The method of claim 46, wherein the advanced human milk fat globule associated disease is breast cancer.

Claim 49 (currently amended): A method for ~~removing~~ promoting clearance of a labeled anti-human milk fat globule (HMFG) antibody that binds to the antibody of claim 1 from the circulation or tissues of an individual who has received [[a]] the labeled anti-HMFG antibody, comprising administering ~~monoclonal~~ the antibody ~~11D10~~ of claim 1 to the individual.

Claim 50 (canceled)

Claim 51 (currently amended): A method for detecting an anti-human milk fat globule immunological response in an individual comprising the steps of (a) contacting a biological sample from the individual with the monoclonal anti-idiotype antibody 11D10 of claim 1 under conditions that permit formation of a stable complex between the monoclonal anti-idiotype antibody ~~11D10~~ and an antibody containing the paratope of the monoclonal anti-idiotype antibody ~~11D10~~; and (b) detecting any of the ~~stable~~ complexes

formed, wherein the presence of the complexes is indicative of the presence of an anti-human milk fat globule immunological response in the individual.

Claims 52-53 (canceled)

Claim 54 (currently amended): A kit comprising the anti-idiotype antibody ~~11D10~~ of claim 1 in suitable packaging.

Claim 55 (currently amended): The kit of claim 54, wherein the antibody ~~11D10~~ comprises a detectable label.

Claim 56 (previously presented): A kit comprising the polypeptide of claim 20 in suitable packaging.

Claims 57-58 (canceled)

Claim 59 (currently amended): A composition comprising an effective amount of the anti-idiotype antibody of claim 1, wherein an effective amount is an amount sufficient to elicit an anti-human milk fat globule immune response.

Claim 60 (previously presented): A composition comprising an effective amount of the antibody of claim 4, wherein an effective amount is an amount sufficient to elicit an anti-human milk fat globule immune response.

Claim 61 (previously presented): A composition comprising an effective amount of the polypeptide of claim 20, wherein an effective amount is an amount sufficient to elicit an anti-human milk fat globule immune response.

Claim 62 (previously presented): The composition of claim 39, wherein the specific immune response comprises production of HMFG-specific antibody.

Claim 63 (previously presented): The composition of claim 39, wherein the specific immune response comprises production of HMFG-specific T cells.

Claim 64 (previously presented): The humanized antibody of claim 35, wherein the specific immune response comprises production of HMFG-specific antibody.

Claim 65 (previously presented): The humanized antibody of claim 35, wherein the specific immune response comprises production of HMFG-specific T cells.

Claim 66 (canceled)

Claim 67 (previously presented): The fusion polypeptide of claim 34, wherein the immunoglobulin constant region is human.

Claim 68 (previously presented): The immunogenic composition of claim 42, further comprising an adjuvant.

Claim 69 (previously presented): The purified antibody of claim 4, said antibody comprising the sequence of SEQ ID NO:2.

Claim 70 (previously presented): The purified antibody of claim 4, said antibody comprising the sequence of SEQ ID NO:4.

Claim 71 (currently amended): The fusion polypeptide of claim 33, wherein the light chain variable region and the heavy chain variable region ~~of antibody 11D10~~ are joined by a linker polypeptide of about 5 to 20 amino acids.

Claim 72 (previously presented): The humanized antibody of claim 35, wherein the framework regions are human sequences.

Claim 73 (currently amended): A humanized antibody comprising three CDRs from the light chain variable region of antibody 11D10, three CDRs from the heavy chain variable region of antibody 11D10, and framework regions that are human sequences, wherein antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020, and wherein the humanized antibody is able to stimulate a specific immune response against human milk fat globule (HMFG).

Claim 74 (previously presented): A composition comprising the purified antibody of claim 4 and a pharmaceutically acceptable excipient.

Claim 75 (previously presented): A composition according to claim 74, wherein the composition is immunogenic.

Claim 76 (previously presented): A composition according to claim 75, further comprising an adjuvant.

Claim 77 (canceled)

Claim 78 (previously presented): A fusion polypeptide according to claim 27, wherein the amino acid sequences of the light chain variable region and the heavy chain variable region are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim 79 (previously presented): A fusion polypeptide according to claim 32, wherein the linker polypeptide comprises the amino acid sequence $(GGGGS)_3$ (SEQ ID NO:35).

Claim 80 (previously presented): A humanized antibody according to claim 35, wherein the light chain variable region of antibody 11D10 and the heavy chain variable region of antibody 11D10 are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim 81 (previously presented): A composition comprising the humanized antibody of claim 35 and a pharmaceutically acceptable excipient.

Claim 82 (previously presented): A composition according to claim 81, wherein the composition is immunogenic.

Claim 83 (previously presented): A composition according to claim 82 further comprising an adjuvant.

Claim 84 (currently amended): A humanized antibody comprising three CDRs from the light chain variable region of antibody 11D10, three CDRs from the heavy chain variable region of antibody 11D10, and framework regions that are human sequences, wherein

antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020, wherein the humanized antibody is able to stimulate a specific immune response against human milk fat globule (HMFG), and wherein the light chain variable region of antibody 11D10 and the heavy chain variable region of antibody 11D10 are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim 85 (previously presented): A composition comprising the humanized antibody of claim 84 and a pharmaceutically acceptable excipient.

Claim 86 (previously presented): A composition according to claim 85, wherein the composition is immunogenic.

Claim 87 (previously presented): A composition according to claim 86, further comprising an adjuvant.

Claim 88 (previously presented): An antibody comprising a light chain variable region amino acid sequence contained in SEQ ID NO:2 and a heavy chain variable region amino acid sequence contained in SEQ ID NO:4, wherein the antibody is able to stimulate a specific immune response against human milk fat globule (HMFG).

Claim 89 (previously presented): A composition comprising the antibody of claim 88 and a pharmaceutically acceptable excipient.

Claim 90 (previously presented): A composition according to claim 89, wherein the composition is immunogenic.

Claim 91 (previously presented): A composition according to claim 90, further comprising an adjuvant.

Claim 92 (currently amended): An isolated antibody comprising three CDRs from the light chain variable region of anti-idiotype antibody 11D10 and three CDRs from the heavy chain variable region of anti-idiotype antibody 11D10, wherein anti-idiotype antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB

12020, wherein the CDRs from the light chain variable region are contained in SEQ ID NO:2 and the CDRs from the heavy chain variable region are contained in SEQ ID NO:4, and wherein the antibody is able to stimulate a specific immune response against human milk fat globule (HMFG).

Claim 93 (previously presented): A composition comprising the antibody of claim 92 and a pharmaceutically acceptable excipient.

Claim 94 (previously presented): A composition according to claim 93, wherein the composition is immunogenic.

Claim 95 (previously presented): A composition according to claim 94, further comprising an adjuvant.

Claim 96 (previously presented): A composition comprising the polypeptide of claim 20 and a pharmaceutically acceptable excipient.

Claim 97 (canceled)

Claim 98 (previously presented): A polypeptide comprising an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of antibody 11D10, or an immunoglobulin variable region containing three heavy chain CDRs of antibody 11D10, wherein antibody 11D10 is produced by a hybridoma cell line designated ATCC NO. HB 12020.

Claim 99 (previously presented): A composition comprising the polypeptide of claim 98 and a pharmaceutically acceptable excipient.

Claim 100 (previously presented): A polypeptide according to claim 98, comprising an immunoglobulin variable region containing the three light chain CDRs of antibody 11D10.

Claim 101 (previously presented): A polypeptide according to claim 98, comprising an immunoglobulin variable region containing the three heavy chain CDRs of antibody 11D10.

Claim 102 (previously presented): A polypeptide according to claim 98, wherein the light chain variable region is contained in SEQ ID NO:2.

Claim 103 (previously presented): A polypeptide according to claim 98, wherein the heavy chain variable region is contained in SEQ ID NO:4.

Claim 104 (previously presented): A polypeptide comprising an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of antibody 11D10 and an immunoglobulin variable region containing three heavy chain CDRs of antibody 11D10, wherein antibody 11D10 is produced by a hybridoma cell line designated ATCC NO. HB 12020, and wherein the light and heavy chain variable region sequences are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively, and wherein the antibody is able to stimulate a specific immune response against human milk fat globule (HMFG).

Claim 105 (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of an antibody according to claim 35 to the individual.

Claim 106 (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of an antibody according to claim 73 to the individual.

Claim 107 (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step

of administering an effective amount of an antibody according to claim 84 to the individual.

Claim 108 (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of an antibody according to claim 92 to the individual.

Claim 109 (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of a polypeptide according to claim 20 to the individual.

Claim 110 (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of a polypeptide according to claim 104 to the individual.

Claims 111-124 (canceled)

Claim 125 (new): The polypeptide of claim 20, wherein the specific immune response comprises production of HMFG-specific antibodies.

Claim 126 (new): The polypeptide of claim 20, wherein the specific immune response comprises production of HMFG-specific T cells.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
October 18, 2004

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
10/18/04